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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/635,003	08/06/2003	Victor Zurita	331202.00009	7483
27160 7590 02/07/2007 PATENT ADMINISTRATOR KATTEN MUCHIN ROSENMAN LLP 1025 THOMAS JEFFERSON STREET, N.W. EAST LOBBY: SUITE 700 WASHINGTON, DC 20007-5201			EXAMINER FIELDS, COURTNEY D	
			ART UNIT	PAPER NUMBER
			2137	
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		02/07/2007	PAPER	

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

# Office Action Summary

Application No.

10/635,003

Applicant(s)

ZURITA ET AL.

Examiner

Courtney D. Fields

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 06 August 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-23 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 20 July 2004.
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- ☐ Notice of Informal Patent Application
- ☐ Other: \_\_\_\_\_.

### DETAILED ACTION

1. Claims 1-23 are pending.

#### ***Information Disclosure Statement***

2. The Information Disclosure Statement respectfully submitted on 20 July 2004 has been considered by the Examiner.

#### ***Claim Rejections - 35 USC § 102***

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 1-23 are rejected under 35 U.S.C. 102(e) as being anticipated by Brinkman et al. (Pub No. 2005/0065818).

Referring to the rejection of claim 1, Brinkman et al. discloses a computer-implemented method of validating a computer system comprising the steps of:

- (i) receiving data representative of a plurality of requirements for said computer system (See page 5, Section 0070)
- (ii) generating a validation plan based on said received data (See page 5, Section 0071)
- (iii) determining a computing environment appropriate to said computer system based on said received data (See page 5, Section 0072)

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(iv) generating a plurality of tests to be performed during an implementation of said validation plan (See page 5, Section 0072)

(v) presenting said tests to a user as part of said implementation (See page 5, Section 0072)

(vi) receiving responses from said user as to a status of said tests (See page 6, Section 0074)

(vii) generating a validation report based on said responses (See page 6, Section 0074)

(viii) presenting a non-validation message if said validation report indicates said system failed one or more of said tests (See page 5, Section 0073)

(ix) presenting a validation message if said validation report indicates said system meets said tests (See page 6, Section 0074)

and, (x) repeating one or more of the foregoing steps until said validation report indicates said system meets said tests (See page 6, Section 0074)

Referring to the rejection of claims 2, 12 and 22, Brinkman et al. discloses a computer-implemented method, apparatus, and readable media of validating a computer system comprising the steps of:

receiving a plurality of validation requirements for said computer system (See page 5, Section 0070)

receiving data representative of the results of performing each validation requirement, said results including whether a particular requirement was achieved and exception reports for each requirement that was not achieved (See page 5, Sections 0072-0073)

and, generating a report for each of said requirements, said report including a message indicating whether said system is validated if a defined set of said requirements are achieved (See page 6, Section 0074)

Referring to the rejection of claims 3 and 13, Brinkman et al. discloses the claimed limitation wherein said computer system is a computer system used in the pharmaceutical industry (See page 4, Section 0059)

Referring to the rejection of claims 4 and 14, Brinkman et al. discloses the claimed limitation wherein said computer system is a computer system used in the health care industry (See page 4, Section 0060)

Referring to the rejection of claims 5 and 15, Brinkman et al. discloses the claimed limitation wherein said validation requirements include at least one of a installation qualification, operational qualification, performance qualification, a third-party qualification (See page 5, Section 0071)

Referring to the rejection of claims 6 and 16, Brinkman et al. discloses the claimed limitation wherein said third-party qualification is based on 21 CFR Part 11 (See page 9, Section 0097)

Referring to the rejection of claims 7 and 17, Brinkman et al. discloses the claimed limitation wherein said installation qualification, said operational qualification, said performance qualification, and said third-party qualification each include at least one of a hardware requirement, a user requirement, a test objective, and a test instruction (See page 4, Section 0064)

Referring to the rejection of claims 8 and 18, Brinkman et al. discloses the

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claimed limitation wherein said validation requirement further includes an audit respective to said installation qualification, said operational qualification, said performance qualification, and said third-party qualification (See page 7, Section 0086)

Referring to the rejection of claims 9 and 19, Brinkman et al. discloses the claimed limitation wherein said audit is comprised of predefined checklist reflecting best practices applicable to an identifiable type of said system (See page 7, Section 0086)

Referring to the rejection of claims 10 and 20, Brinkman et al. discloses the claimed limitation wherein said report indicates that said requirements are not achieved unless an affirmative response that each requirement was achieved has been received (See page 7, Section 0085)

Referring to the rejection of claims 11 and 21, Brinkman et al. discloses the claimed limitation wherein comprising the additional step of presenting a report summarizing each of said requirements (See page 7, Section 0086)

Referring to the rejection of claim 23, Brinkman et al. discloses a method of restricting access to a computing apparatus comprising the steps of:

delivering a computer-based training session to a user, said session for instructing said how to operate said apparatus (See page 7, Section 0089)

generating a unique user code respective to said user provided said user successfully completes said training session (See page 7, Section 0089)

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presenting a user-login dialogue on said apparatus, said dialogue requesting an identification of said user and said user code (See page 8, Section 0090)

allowing access to said computing apparatus if a received identification and a received user code match said user and said user code and otherwise refusing access to said computing apparatus (See page 8, Section 0091)

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Courtney D. Fields whose telephone number is 571-272-3871. The examiner can normally be reached on Mon - Thurs. 6:00 - 4:00 pm; off every Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Emmanuel Moise can be reached on 571-272-3865. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

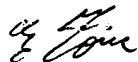
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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



cdf

February 3, 2007



EMMANUEL L. MOISE  
SUPERVISORY PATENT EXAMINER